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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/229,751 01/14/99 TURNBROUGH

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HM12/0302

EXAMINER

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WESSENDORF, T

ART UNIT	PAPER NUMBER
1627	6

DATE MAILED:

03/02/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. 09/229,751	Applicant(s) Turnbough
	Examiner T. Wessendorf	Group Art Unit 1627

Responsive to communication(s) filed on Nov 2, 1999

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle* 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claim

Claim(s) 1-20  is/are pending in the application.

Of the above, claim(s) 1-9, 14, 16, 17, 19, and 20  is/are withdrawn from consideration.

Claim(s)  is/are allowed.

Claim(s) 10-13, 15, and 18  is/are rejected.

Claim(s)  is/are objected to.

Claims  are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on  is/are objected to by the Examiner.

The proposed drawing correction, filed on  is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number)

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received:

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s).

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

*Sequence Listing Error Report*

**-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --**

Art Unit: 1627

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Printout of Raw Sequence Listing Error Summary Report.

Applicant's election of Group III, claims 10-13 in Paper No. 5 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-9, 14, 16-17 and 19-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. Election was made **without** traverse in Paper No. 5. Accordingly, claims 10-13, 15 and 18 are under consideration. [Note that the amendment of 11/1/99 included claim 10. But there is no indication to amend or that this is an amended claim]. Accordingly, this claim has not been entered and the original claim 10 is the one under consideration.]

Art Unit: 1627

The specification is objected to because of the following informalities:

1. There is no Seq. ID. No. for peptide sequences Ser-Pro-Leu-X<sub>1</sub>-X<sub>2</sub> recited at e.g., page 2, lines 35-36.
2. Typographical errors and syntax errors, example of typographical errors are: "devise" at page 3, line 30 (should be device); "cones" at page 12, line 31. Example of syntax error is "the peptides could also be used antigens.." at e.g., page 4, lines 3-4. See also page 13, lines 37-39.
3. The sentence " In order to identify the receptor that interacts with the peptide, biotin-containing cross-linking agent that has been attached to a tight-binding peptide." is incomplete. (See e.g., page 9, lines 22-24). Also, the sentence at page 11, line 22 is incomplete.

The use of the trademark e.g., TWEEN at page 5, line 29 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Art Unit: 1627

The specification has not been checked to the extent necessary to determine the presence of **all** possible minor errors ( grammatical, typographical and idiomatic). Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-13, 15 and 18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific ligand that can bind a specific type of bacteria, *Bacillus*, does not reasonably provide enablement for any kind of ligand bound solid support that can bind any kind of bacterial spores. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The scope of enabling disclosure is not commensurate in scope with the scope of the claimed composition drawn broadly to any kind of ligand linked to a solid support that binds to any

Art Unit: 1627

kind of bacterial spores. The specification discloses specific ligands that bind to a particular kind of bacteria i.e., the *Bacillus*. There is no indication in the specification that the composition and procedure obtained for the particular composition are generally applicable to all or any kinds of ligand binding bacteria. There is no description of any ligand binding bacterial spores encompassed by the broadly claimed invention. The claimed bacterial spores and ligand that binds to them which would include an innumerable kinds of ligands and/or bacteria. The disclosure lacks guidance that would aid or lead one skilled in the art to any other ligand binding bacterial spores especially in view of the findings in the disclosure e.g., page 7, lines 16-19 that attempts to bind the spores of *B. Subtilis* with a 4-mer peptide NHFL showed said sequence to be a poor ligand. See also, Cole (Jrnl. Of Clinical Microbiology) at e.g., age 48; Pistole (Ann. Rev. Microbiol.) at e.g., page 108 or Krishnamurthy (Rapid Comm. In Mass spectrometry) at e.g., page 1992. If applicant has already encountered such difficulty for a very specific bacteria and a specific 4-mer peptide sequence, how much more with one skilled in the art given little or no guidance? As applicant discloses in the specification in order to successfully identify disease causing bacteria, such bacterial spores should bind with such great avidity and specificity to enable separation and

Art Unit: 1627

identification of the particular desired bacteria. But it would appear that a skilled artisan would have to take undue amount of experimentation to determine the numerous undefined parameters encompassed by the broadly claimed composition. *Ex parte Forman*, 230 USPQ 546, BPAI, 1986.

Claims 10-13, 15, 18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification fails to teach how to make and use a composition of matter comprising of solid support wherein the solid supports takes the different forms of a tape, sponge or filter. Except for the general statements contain in the specification, there is no description as to the kind or type of solid support or how such solid support assumes the different forms.

Art Unit: 1627

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-13 , 15 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claim 15 is indefinite as to the components that comprise the composition of matter. Is the composition comprise of a peptide ligand and the sample? Within the claimed context, what would be the metes and bounds of the term "matter", (especially in the absence of positive support of said term in the specification)?

2. Claims 12-13 do not further limit the composition in the recitation of the different forms by which the solid support assumes.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1627

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371<sup>®</sup> of this title before the invention thereof by the applicant for patent.

Claims 10, 15 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Ezzell et al (Jrnl. of Clinical Microbiology).

Ezzell discloses a composition comprising peptide ligand i.e., a monoclonal antibody that binds to Bacillus spores and a sample suspected of containing said Bacillus spores. See particularly, page 223, abstract; page 226, col. 1 up to page 228, col. 1. The claimed composition is therefore fully met by the composition of Ezzell.

Claims 10-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Hutchens et al (5,719,060).

Hutchens discloses at e.g., col. 23, Example 3 up to col. 24, line 30 composition comprising of a peptide ligand linked to a polymeric solid support. The broadly claimed composition is therefore anticipated by the specific composition of Hutchens.

Art Unit: 1627

The recitation of the functional limitation in a composition does not make the composition different as the components of the composition are the same.

Claims 10, 15, 18 are rejected under 35 U.S.C. 102(a) as being anticipated by either D' Mello et al (Virology) or applicant's disclosure of known art.

D'Mello discloses at e.g., page 320, cols. 1 and 2; page 322, cols. 1 and 2 composition comprising of a peptide ligand linked to a polymeric solid support. Applicant admits at e.g., page 2, lines 4-5 that "...the peptides are included in phage display peptide libraries that, are commercially available...." Furthermore, at page 4, second complete paragraph applicant admits that " phage display ligand screening was employed using a commercially available combinatorial library of ..random peptide sequences.." See also page 5. The broadly claimed composition is therefore anticipated by the specific composition of D'Mello or the art cited by applicant. The recitation of the functional limitation in a composition does not make the composition different as the components of the composition are the same.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

1. Salonen discloses a human recombinant virus antibodies and cross -reaction with other hantaviruses.

Art Unit: 1627

2. Morgan discloses detection of chemical markers of m.o. by GC-M.S.

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1627.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. Wessendorf whose telephone number is (703) 3967. The examiner can normally be reached on Mon. to Fri. from 8 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald E. Adams, Ph.D., can be reached on (703) 308-0570. The fax phone number for this Group is (703) 308-7924.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Tdw

1/28/00

*T. Wessendorf*  
Patent Examiner